

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1984
ANSWERED ON:16.03.2005
SPECIFIC GUIDELINES FOR SMALL PHARMA UNITS
Shakya Shri Raghuraj Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) Whether the Government has provided specimen documentation proforma required to be maintained in order to comply with the provisions of GSR 894(E) notification;
- (b) if so, the details thereof; and
- (c) the steps taken by the Government to prevent exploitation and harassment of small pharma manufacturing units by the concerned staff in the absence of such specific guidelines?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a): Yes, Sir.

(b): According to the revised Schedule M (Good Manufacturing Practices) and Schedule U of the Drugs & Cosmetics Rules, following documents are to be maintained by the manufacturers:

- (i) Master Formula Records
- (ii) Batch Manufacturing Records
- (iii) Records of raw materials
- (iv) Batch Packaging Records
- (v) Records of analysis
- (vi) Site Master File
- (vii) Manufacturing Records relating to manufacture of sterile products
- (viii) In-process records
- (ix) Distribution records
- (x) Standard Operating Procedures for different activities.

(c): Under the Drugs and Cosmetics Act, 1940, the responsibility for regulating manufacture and sale of drugs rests with the State Governments. No such specific information of exploitation and harassment of small Pharma manufacturing units by the concerned staff have been received till date.